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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,270	11/08/2001	Gregory S. Hageman	020618-000120US	3566

20350 7590 03/22/2005

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,270	HAGEMAN ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10,11,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10,11,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 9/08/04. Applicant has amended claims 1-5. Claims 21-22 are added. Claims 1-5, 10-11 and 21-22 are pending.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

4. The Office acknowledges the change in the title.

5. The Office acknowledges the drawings submitted on 11/08/2001.

Claim Rejections - 35 USC § 112, second paragraph withdrawn

6. The rejection of claims 1 and 10-11 under 35 U.S.C. 112, second paragraph, as being indefinite for the reference to "stringent conditions" is with drawn in light of Applicants amendments to the claims.

Claim Rejections - 35 USC § 101, maintained

7. Claims 1-5, 10-11 and 21-22 (newly added) stand rejected under 35 USC 101 for lack of utility, for reasons set forth in Office Action mailed 3/8/2004 (see pages 4-8). Applicant's arguments filed on 9/08/04 in reference to claims 1-5, 10 and 11 have been fully considered but they are not persuasive.

Applicants have traversed this rejection on the premise that the application provides "reasonable correlation" between the activity in question and the asserted utility. Applicants contend, that the instant application does in fact establish a

"reasonable correlation" between the asserted activity and stated activity. Thus, it is claimed that it is sufficient to satisfy the credibility prong of the utility analysis. Applicants' arguments have been fully considered but are not deemed persuasive.

While it is true that the Applicant need only provide a "reasonable correlation" between the role of the proteins encoded by the claimed nucleic acids and the asserted diagnostic and/or therapeutic utilities, Applicants have failed provide this correlation. Applicants contends that the currently claimed nucleic acids play a role in retinal adhesion and as such are associated with certain ocular disorders such as retinal detachment, chorioretinal degeneration and macular degeneration. This remains a conjecture because IPM150 is found to be expressed in the retina along with kidney, liver, small intestine, thymus and lung tissues (paragraph 82). In addition, Applicants have not provided any pathological processes associated with the IPM150. In fact, Applicants own published work observed that the "data presented represented a first step towards the development of experimental murine models, which may eventually be used to elucidate the mechanisms underlying retinal adhesion and photoreceptor survival (Kuehn et al. 2000). The employment of the nucleotide encoding this protein (IPM150) only as the subject of further research does not satisfy the utility requirement of 35 USC 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form" (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)).

Applicants have discussed the possible location of the instant matrix protein (IPM150) in the specification and remarks filed 9/8/2004 (se pages 10 and 11). Based

on the location of the protein Applicants argue that the instant protein plays a role retinal adhesion and promoting photoreceptor viability. Thus, it is concluded that it is useful in the diagnosis and /or treatment of various ocular disorders (see page 11 of the remarks). However, as indicated in the Office action mailed 03/08/2004 neither the specification nor the prior art provides a nexus between the claimed polypeptide with any of the conditions or disorders contemplated by the instant specification, therefore, there is no evidence of record that would provide for a method of treating and/or diagnosing any of the listed conditions or disorders.

Applicants argue that the Office Action has failed to address whether the use of the asserted nucleic acids as part of a nucleic acid array is a credible utility. Applicants contends that IPMC polynucleotide sequences can also be combined with nucleic acids from other genes having roles in ocular diseases or disorders in an array that are specifically designed for analyzing ocular disease related gene expression. It is asserted that such arrays are useful for analyzing ocular diseases such as retinal detachment. Appellants' arguments have been fully considered but have not been found to be persuasive. While the examiner agrees that any polynucleotide, including the claimed polynucleotides, can be used in a cDNA microarray, such does not confer patentable utility on the claimed polynucleotides. Since any polynucleotide can be used in a microarray, such a use is not specific to the claimed polynucleotides. Just as any orphan receptor can be used in an assay to screen for ligands, such does not confer patentable utility on a particular orphan receptor. Such can be done with any orphan receptor, and thus the asserted utility is not specific. Furthermore, since the

specification does not disclose a correlation between any disease or disorder and an altered level or form of the claimed polynucleotides, the results of gene expression monitoring assays would be meaningless without significant further research. Therefore, the asserted utility is also not substantial.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson*, *ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be useful in the diagnosis and /or treatment of various ocular disorders is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a fuel source.

Claim Rejections - 35 USC § 112, first paragraph, maintained.

8. Claims 1-5, 10-11 and 21-22 (newly added) stand rejected under 35 USC 112, first paragraph is maintained for reasons set forth in the Office Action of 3/08/04 and paragraph 7 above. Applicant's arguments filed on filed on 9/08/04 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102, maintained

9. The rejection of claims 1-3 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo et al. (1996).

Applicants' amendments and argument have been fully considered but are not persuasive with respect to claims 1 and 10-11 because the fragment (540bps long) described by Bolando et al. will hybridize under the conditions described to SEQ ID NO: 1 of the instant invention containing the fragment described Bolando et al (see Appendix A).

10. No claims are allowable.

11. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 03/05

JANET ANDRES
PRIMARY EXAMINER

Applicants Copy

Appendix A


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RESULT 11
BM690735
LOCUS       BM690735                675 bp    mRNA    linear   EST 28-FEB-2002
DEFINITION  UI-E-CK0-aav-c-12-0-UI.r1 UI-E-CK0 Homo sapiens cDNA clone
            UI-E-CK0-aav-c-12-0-UI 5', mRNA sequence.
ACCESSION   BM690735
VERSION     BM690735.1  GI:19003993
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 675)
  AUTHORS   Bonaldo,M.F., Lennon,G. and Soares,M.B.
  TITLE     Normalization and subtraction: two approaches to facilitate gene
            discovery
  JOURNAL   Genome Res. 6 (9), 791-806 (1996)
  MEDLINE   97044477
   PUBMED   8889548
COMMENT     Contact: Soares, MB
            Coordinated Laboratory for Computational Genomics
            University of Iowa
            375 Newton Road , 4156  MEBRF, Iowa City, IA 52242, USA
            Tel: 319 335 8250
            Fax: 319 335 9565
            Email: bento-soares@uiowa.edu
            Tissue Procurement: Dr. Gregg Hageman
             cDNA Library preparation: Dr. M. Bento Soares, Univeristy of Iowa
             cDNA Library Arrayed by: Dr. M. Bento Soares, Univeristy of Iowa
             DNA Sequencing by: Dr. M. Bento Soares, Univeristy of Iowa
             Clone Distribution: Researchers may obtain clones from Research
            Genetics (www.resgen.com).
            Seq primer: M13 Reverse.
FEATURES             Location/Qualifiers
     source          1. .675
                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="UI-E-CK0-aav-c-12-0-UI"
                     /tissue_type="Retina Foveal and Macular"
                     /dev_stage="adult"
                     /lab_host="DH10B (Life Technologies) (T1 phage resistant)"
                     /clone_lib="UI-E-CK0"
                     /note="Organ: eye; Vector: pT7T3-Pac (Pharmacia) with a
                     modified polylinker; Site_1: EcoR I; Site_2: Not I;
                     UI-E-CK0 is a cDNA library containing the following
                     tissue(s): Retina Foveal and Macular. The library was
                     constructed according to Bonaldo, Lennon and Soares,
                     Genome Research, 6:791-806, 1996. First strand cDNA
                     synthesis was primed with an oligo-dT primer containing a
                     Not I site. Double stranded cDNA was ligated to an EcoR I
                     adaptor, digested with Not I, and cloned directionally
                     into pT7T3-Pac vector. The oligonucleotide used to prime
                     the synthesis of first-strand cDNA contains a library tag
                     sequence that is located between the Not I site and the
                     (dT)18 tail. The sequence tag for this library is GTCC.
                     This library was created for the program, Gene Discovery
                     in the Visual System, supported by National Eye Institute
                     (NEI)."
ORIGIN

  Query Match           17.7%;  Score 589.4;  DB 12;  Length 675;
  Best Local Similarity   99.7%;  Pred. No. 2.1e-120;
  Matches  601;  Conservative    0;  Mismatches    1;  Indels    1;  Gaps    1;

Qy       2728 CAAATATAGAAGAGTCATGTACTTGGCAACCAGTAAATTCTGAAAAAAAAGACACTTACT 2787
             |||||||||||||| |||||||||||||||||||||||||||||||||||||||||||||||
Db          8 CAAATATAGAAGA-TCATGTACTTGGCAACCAGTAAATTCTGAAGAAAAAGACACTTACT 66

Qy       2788 TATTATTAAAACCCCAAATGCAATCAGCGAAACATATTTTTACTATTCTTGGATGATAGT 2847
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         67 TATTATTAAAACCCCAAATGCAATCAGCGAAACATATTTTTACTATTCTTGGATGATAGT 126

Qy       2848 CAAAATGATCATAAGCCAGGTTTGCTTCCACCTTCCCTGAAAATTTTACTCACAGATCAT 2907
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy       2908 TTGCAACAAGCATAGCTTACTTATTGTTTAGGGACTGAACAATTTATTGGGAAGCAAACT 2967
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy       2968 CTTTATATGCTAGAAAGTACATTTAAAAGATGACTACTTACGCAGGGAGATGCAGGTCTC 3027
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        247 CTTTATATGCTAGAAAGTACATTTAAAAGATGACTACTTACGCAGGGAGATGCAGGTCTC 306

Qy       3028 TCTAAACGCATGAATGTATGTAGTGTGTAGGCACTGTAGTGAGTGTATATATGCTCCACA 3087
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        307 TCTAAACGCATGAATGTATGTAGTGTGTAGGCACTGTAGTGAGTGTATATATGCTCCACA 366

Qy       3088 CTACGTCTGATAAACACAAACCTCAGTATTCAGTTATTAGGCACACTAGTTTTATACGCA 3147
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        367 CTACGTCTGATAAACACAAACCTCAGTATTCAGTTATTAGGCACACTAGTTTTATACGCA 426

Qy       3148 ACTACTGCTTACATAGTAGACTGTTTTGTTGCCAATAATCTTTGAATTGTTCTTTAAAAG 3207
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        427 ACTACTGCTTACATAGTAGACTGTTTTGTTGCCAATAATCTTTGAATTGTTCTTTAAAAG 486

Qy       3208 AAACTGAGGTTCAGATACACATACCATGGAAAAATCTTACTTTTCTTGTTACTACACAAA 3267
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        487 AAACTGAGGTTCAGATACACATACCATGGAAAAATCTTACTTTTCTTGTTACTACACAAA 546

Qy       3268 GCTATTTTAAAGAAGATGCTATGTTGGGAGAAGGGCGAAGTTGTACTATATGACATAATC 3327
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        547 GCTATTTTAAAGAAGATGCTATGTTGGGAGAAGGGCGAAGTTGTACTATATGACATAATC 606

Qy       3328 AAT 3330
             |||
Db        607 AAT 609


RESULT 12
BQ636596
LOCUS       BQ636596                598 bp    mRNA    linear   EST 15-JUL-2002
DEFINITION  hd11h02.y1 Human Retina cDNA (Un-normalized, unamplified): hd/he
            Homo sapiens cDNA clone hd11h02 5', mRNA sequence.
ACCESSION   BQ636596
VERSION     BQ636596.1  GI:21761055
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 598)
  AUTHORS   Wistow,G., Bernstein,S.L., Wyatt,M.K., Ray,S., Behal,A.,
            Touchman,J.W., Bouffard,G., Smith,D. and Peterson,K.
  TITLE     Expressed sequence tag analysis of human retina for the NEIBank
            Project: Retbindin, an abundant, novel retinal cDNA and alternative
            splicing of other retina-preferred gene transcripts
  JOURNAL   Mol. Vis. 8 (4), 196-204 (2002)
  MEDLINE   22103461
   PUBMED   12107411
COMMENT     Contact: Wistow G
            Section on Molecular Structure and Function
            National Eye Institute
            6/331, NIH, Bethesda, MD 20892-2740, USA
            Tel: 301 402 3452
            Fax: 301 496 0078
            Email: graeme@helix.nih.gov
            Plate: 11  row: h  column: 02
            Seq primer: M13RP1 reverse primer (ABI).
FEATURES             Location/Qualifiers
     source          1. .598
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                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="hd11h02"
```